REMARKS

Previously claims 4, 5, 15, 17, 18, 20-27, 30-40, 42, and 43 were pending. In the instant amendment, claim 23 is canceled without prejudice to Applicants' right to pursue canceled subject matter in one or more other applications. Claim 30 has been amended. After entry of the amendment, claims 4, 5, 15, 17, 18, 20-22, 24-27, 30-40, 42, and 43 are pending and under consideration.

I. CLAIM AMENDMENTS

Claim 23 has been canceled, without prejudice.

Claim 30 has been amended to an independent form.

As these amendments do not add new matter and are supported by the specification and claims as originally filed, entry of the amendment is respectfully requested.

No amendment fee is believed to be due.

II. CLAIM REJECTION UNDER 35 U.S.C. § 103(a)

Claims 4, 5, 15, 17, 18, 23, 26, 27, 32, 38, 42, and 43 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Fujiwara *et al.*, 1985, *Cancer Research* 45: 5442-5446, in view of Spector (U.S. Patent No. 3,976,763,) and Wong, 1991, *Chemistry of Protein Conjugation and Cross-Linking*, CRC Press, pp. 63-67, and Applicant's alleged admission on page 2 of the specification. The rejection of claim 23 is moot in view of the cancellation of claim 23. Applicants respectfully traverse the rejections of base claim 15, and of claims 4, 5, 17, 18, 26, 27, 32, 38, 42, and 43 that depend from claim 15.

Among the factual inquiries for determining obviousness under 35 U.S.C. § 103 enunciated by the Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. (1966) is that of ascertaining the differences between the prior art and the claims at issue. As elaborated by the Federal Circuit in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), the prior art must be considered in its entirety, including disclosures that teach away from the instant claims. *See also Rockwell International Corp. v. United States*, 147 F.3d 1358, 1365, 47 U.S.P.Q.2d 1027, 1031 (Fed. Cir. 1998) ("In determining obviousness, the invention must considered as a whole without the benefit of hindsight, and the claims must be considered in their entirety."). Applicants respectfully submit that

consideration of the full disclosures of Fujiwara *et al.* and Spector reveals that these references cited by the Patent Office teach away from base claim 15 when claim 15 is considered in its entirety, and therefore the rejected claims are not obvious in view of the cited references.

Fujiwara *et al.* and Spector each disclose a conjugate for use as an antigen in eliciting an immune response for preparation of antiserum in rabbits. The bovine serum albumin carrier protein for the haptens disclosed in Fujiwara *et al.* and Spector aids in increasing the immunogenic response by being foreign or exogenous to the host animal.[1] For example, Spector at column 1, lines 55-59, states that the carrier protein should "have the property of independently eliciting an immunogenic response in a host animal," that is, the carrier protein should be exogenous to the host animal.

In contrast, claim 15 recites a conjugate useful for treating a disease selected from the group consisting of tumoral, infectious, and autoimmune disease in a subject comprising, *inter alia*, a native human serum albumin that is *not* regarded as exogenous by the subject. Applicants respectfully submit that one of ordinary skill in the art reading Fujiwara *et al.*, Spector, and Wong would be led away from instant claim 15 since the carrier molecules for the haptens disclosed in Fujiwara *et al.* and Spector should be *exogenous* to the animal host in order to maximize the immune response as opposed to the subject matter of the pending claims which recite a native human serum albumin that is *not* regarded as exogenous by the subject.

Spector teaches a conjugate of chlorpormazine linked to bovine serum albumin and its use in eliciting an immune response for production of antibodies that react with the conjugate. The Patent Office alleges that linking an active substance to human serum albumin is suggested by Spector who states "[e]xamples of preferred proteins useful in the practice of this invention include the serum proteins preferably mammalian serum proteins, such as, for example, ... human serum albumin ..."

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[1] Fujiwara *et al.*, as acknowledged by the Patent Office, does not teach a conjugate comprising a human serum albumin, which is an element of the conjugate recited in claim 15. (*See* Office Action of June 2, 2003, page 4, first sentence). Thus, it is confusing why the Office Action states in the last sentence on page 4 that "[a]bsent objective evidence to the contrary, the human serum albumin of the primary reference is not regarded as exogenous by the subject" since Fujiwara *et al.* does not teach a human serum albumin, and moreover, the carrier protein should be regarded as exogenous by the subject, as explained in Spector.

(Spector, col. 2, lines 1-6). Continuing, however, Spector states that "[i]t is generally preferred that proteins be utilized which are *foreign to the animal host* in which the resulting antigen will be employed" (Spector, col. 2, lines 7-10) (emphasis added). The animal hosts listed in Spector, column 3, lines 58-61, include rabbits, horses, etc., but not humans. As taught by Spector, the antigen clearly must be intended for use in one of these non-human hosts. *See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) (explaining that the prior art must be considered in its entirety, including disclosures that teach away from the instant claims). In contrast, the conjugate of claim 15 comprises a human serum albumin that is not regarded as exogenous by the subject. Therefore, Applicants submit that one of skill in the art, upon reading the full disclosures of Fujiwara *et al.* and Spector, would be led away from conjugate of claim 15 in an attempt to develop an conjugate useful for treating a disease selected from the group consisting of tumoral, infectious, and autoimmune disease in a subject.

The cited reference of Wong merely discloses a large number of reagents that can be used to cross-link proteins and does not bear upon the fact that Fujiwara *et al.* and Spector teach away from claim 15. Nor does the fact that a variety of active substances are known in the art, even had Applicants made such a statement in the specification, bear upon the fact that Fujiwara *et al.* and Spector teach away from claim 15.

For these reasons, Applicants respectfully submit that ascertaining the differences between the full disclosure of the prior art and claim 15 warrants the conclusion that claim 15 is not obvious over Fujiwara *et al.*, in view of Spector, Wong, and any statements made by Applicants in the instant specification. Similarly, claims 4, 5, 17, 18, 26, 27, 32, 38, 42, and 43 that depend from claim 15 are not obvious. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 4, 5, 15, 17, 18, 23, 26, 27, 32, 38, 42, and 43 under 35 U.S.C. § 103(a).

III. CLAIMS 20-22, 24, 25, 30, 31, 33-37, 39, AND 40

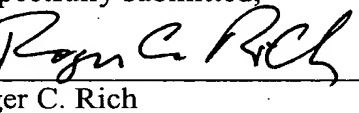
It is Applicants' understanding that no objections or rejections stand against claims 20-22, 24, 25, 30, 31, 33-37, 39 and 40. Although claims 20-22, 25, 31, 33-37, 39 and 40 depend from claim 15, Applicants submit that, for the reasons stated above in Section II, none of these claims is obvious under 35 U.S.C. § 103(a) over the

references cited by the Patent Office. Applicants respectfully request notification that claims 20-22, 24, 25, 30, 31, 33-37, 39 and 40 are allowable.

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney if a telephone call could help resolve any remaining items.

No fees other than those for the Petition for Extension of Time are believed due with this response. However, the Commissioner is authorized to charge any fees under 37 C.F.R. § 1.17, any underpayment of fees, or credit any overpayment to Pennie & Edmonds$_{LLP}$ U.S. Deposit Account No.16-1150 (order no. 8484-084-999) that may be required by this paper.

Date:	November 26, 2003	Respectfully submitted, 	54,398
		Roger C. Rich	(Reg. No.)
		For: Nikolaos C. George (Reg. No. 39,201) **PENNIE & EDMONDS** LLP 1155 Avenue of the Americas New York, New York 10036-2711 (212) 790-9090	